# Flexibilities under Trips: Implementation Gaps between Theory and Practice

by

Muhammad Zaheer Abbas* Shamreeza Riaz**

*mailto:m.zaheer@iiu.edu.pk. Muhammad Zaheer Abbas is a PhD Scholar and Research Associate at the Department of Law, Faculty of Shariah & Law, International Islamic University Islamabad.

**Shamreeza Riaz is a PhD Scholar and Research Associate at the Department of Law, Faculty of Shariah & Law, International Islamic University Islamabad. The authors are grateful to Dr. Hafiz Aziz-ur-Rehman, Assistant Professor, for his guidance, invaluable comments, suggestions and insights. The authors also owe a debt of gratitude to Mr. Shamnad Basheer, Ministry of Human Resource Development Chaired Professor in IP Law, the West Bengal National University Juridical Sciences, Kolkatta, India, for his long distance research assistance and to Dr. Katja Lindroos, Editor-in-Chief, Nordic Journal of Commercial Law for her valuable comments and suggestion on earlier draft. The authors, however, remain personally responsible for any errors or omissions.

# 1 Introduction

Agreement on Trade Related Aspects of Intellectual Property (hereinafter TRIPS) aimed at fostering innovation and developing a system based on innovation-oriented national economies. TRIPS could have enabled all member states to achieve economic development had the enforcement mechanisms been properly implemented. But owing to varying level of development of the member states, the system lacked balance and its implementation was open to abuse.[1] When TRIPS Agreement was concluded, the problems faced by the third world countries, especially due to outbreak of epidemics and pandemics, were not foreseen and public health concern was not given due importance. Instead of having mechanisms in favor of access to essential medicines in its main provisions, the TRIPS included them as exceptions. Compulsory licensing[2] and parallel importation[3] are two such flexibilities provided to the low-income countries.[4]

[1] N. Ayse Odman, 'Using Trips To Make The Innovation Process Work', 2 http://papers.ssrn.com/sol3/papers.cfm?Abstract_id=238988, Accessed 20 Jan 2013.

[2] Compulsory license is a non-voluntary license issued by the state to a third party without authorization of the patent holder on the condition of payment of a reasonable royalty to the patentee. The concept, though in conflict with the exclusive right of the patent holder, was introduced in the U.K in the Statute of Monopolies 1623 as a safeguard to prevent abuses of monopoly rights. Since then, this concept has been endorsed by all important international conventions and treaties on the subject.
The birth of the concept of compulsory licenses is linked to the obligation, introduced by the United Kingdom (UK) Statute of Monopolies in 1623. Compulsory licensing has been reported to be popular in Britain as early as 1850s. Later it was recognized by the international community through Paris Convention of 1883.
For details visit doi:http://www.legislation.gov.uk/aep/Ja1/21/3/contents, accessed 13 Feb, 2012.

[3] A parallel import is a non-counterfeit product imported from another country without the permission of the intellectual property owner. Parallel imports are often referred to as 'grey product'. The practice of parallel importing is often advocated in case of software, music, printed texts, and electronic products and occurs for several reasons. It involves bringing in products from a third party in another country at relatively inexpensive price. The companies set different prices for the same product in different countries. The purchaser from a third party other than the manufacturer can take advantage from this fact. For instance, according to a study in 1998, the price of Smithkline Beechman's version of Armoxil was $8 in Pakistan, $14 in Canada, $16 in Italy, $22 in New Zealand, $29 in the Philippines, $36 in Malaysia, $40 in Indonesia, and $50 in Germany. Certainly, the actual production cost is same for any market but the logic of price difference is to allow an elevated price to recover costs of research and development from the developed world. There may be various other reasons for price difference in different countries.
For more details, see Black's Law Dictionary (6th ed. 1990), 1143

[4] TRIPS, however, does not explicitly establish compulsory licensing rules. Article 31 indirectly authorizes compulsory licensing by allowing 'other use of the subject matter of patents without authorization of the right holder'. Full text of TRIPS Agreement is accessible at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf accessed 13 Jan3,2013.

TRIPS Agreement –one of the most comprehensive treaties on intellectual property rights- introduced a strict legal regime for the protection of IPRs. Prior to TRIPS, pharmaceuticals were excluded from patent protection in domestic laws of about fifty countries. Even many of the present world's developed countries excluded pharmaceutical products from patent protection prior to TRIPS.[5] TRIPS Agreement provided protection to patents[6] in all fields of technology, including pharmaceuticals, for a period of twenty-years.[7] Higher price of drugs due to monopoly provided to the patent holders became a common concern of developing countries considering stronger IPRs protection.[8]

Compulsory licensing safeguard initially provided under TRIPS had no practical significance for least developed countries (hereinafter LDCs) which lacked manufacturing capacity of their own because the pharmaceutical products manufactured under compulsory license could only be used for domestic use. With the outbreak of epidemics and pandemics like HIV/AIDS in Africa, the outcry by NGOs and human rights activists succeeded to draw attention of the world community towards practical problems faced by the LDCs (lacking manufacturing capacity) despite the flexibilities provided in the TRIPS. Changes were made in the existing system under Doha Declaration 2001[9], and WTO[10] Waiver Decision 2003[11] to address the

[5] Germany excluded pharmaceuticals from patent protection until 1968, Switzerland until 1977, Italy until 1978, Norway, Portugal and Spain until 1992, Finland until 1995. See F M Scherer: Jayashree Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries', *Commission on Macroeconomics and Health*, (2001), 4,last accessed date March 23,2012, doi:http://www.icrier.org/pdf/jayawatal%20.pdf.

[6] A grant of right to exclude others from making, using or selling one's invention and includes right to license others to make, use or sell it. *Black's* Law Dictionary (6th ed. 1990), 1125.
A patent is a form of intellectual property. It consists of a set of exclusive rights granted by a sovereign state to an inventor or their assignee for a limited period of time in exchange for the public disclosure of an invention.

[7] Twenty years term of protection is under Article 33 of TRIPS Agreement. Full text of TRIPS Agreement is accessible at. http://www.wto.org/english/docs_e/legal_e/27-trips.pdf accessed 20 20 Jan, 2013. See more Sandra Bartelt, 'Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health', (2003), 6 JWIP 2, 283, doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2003.tb00202.x/pdf, Accessed 20 Jan 2013.

[8] Richard P. Rozek, 'The Effects of Compulsory Licensing on Innovation and Access to Health Care',(2000), 3 JWIP 6,892, doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2000.tb00158.x/pdf, Accessed 20 March 2012.

[9] The November 2001 Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001. It reaffirmed flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines.

[10] The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations. It intends to supervise and liberalize international trade. The organization officially commenced on January 1, 1995 under the Marrakech Agreement, replacing the General Agreement on Tariffs and Trade (GATT). For details visit http://www.wto.org/.accessed20 Jan, 2013.

problems of the LDCs by allowing export of generics produced under compulsory licensing to these countries.

Whether the changes were substantial or cosmetic and to what extent the third world countries have been able to use these flexibilities and mechanisms is a debatable issue. Purpose of this work is to explore the practical implications faced by the poorer countries in availing the legitimate flexibilities provided under TRIPS and to discuss the implementation gaps between theory and practice of compulsory licensing.

## 2 Impediments in the Implementation of TRIPS Flexibilities

TRIPS Agreement is criticized by many for protecting the interests of the rich countries and giant pharmaceutical companies without giving due consideration to the costs of implementing TRIPS for low and middle economy countries with weak innovation capacity and improper legal, administrative and enforcement infrastructure. Owing to weak innovation capacity of their own, majority of patent owners in the third world are foreign inventors; most of the benefits of stringent patent laws therefore flow out into foreign pockets.[12] Access to essential drugs, due to limited purchasing power of masses in the third world, is also a major concern and a much debated issue.

Keeping in view the situation of poorer countries, some flexibilities were provided, under the Doha Declaration, within TRIPS Agreement like 'compulsory licensing' and 'parallel importation'. The Doha Declaration is not self-executing and requires changes in the national laws for its implementation.[13] Most of the third world countries have updated their intellectual property laws in order to conform with TRIPS obligations[14] and to avail the flexibilities afforded by the TRIPS Agreement.

[11] Full text of WTO's General Council's Waiver Decision of August 30, 2003 is available online at <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm>, accessedMay 26, 2012.

[12] Travis j. Lybbert, 'On assessing the cost of TRIPS Implementation', (2002), World Trade Review310, doi:http://journals.cambridge.org/action/displayFulltext?type=1&pdftype=1&fid=142116&jid=WTR&volumeId=1&issueId=03&aid=142115, Accessed 20 March 2012.

[13] South Bulletin, 'The Doha Declaration on TRIPS: The State of Implementation', 6doi:http://www.southcentre.org/index.php?option=com_content&view=article&id=1657%3Asb58&catid=144%3Asouth-bulletin-individual-articles&Itemid=287&lang=en, Accessed 20 March 2012.

[14] Assafa Endeshaw, 'Asian Perspectives on Post-TRIPS Issues in Intellectual Property',(2008), 8 JWIP 2,234, doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2005.tb00247.x/pdf, Accessed 23 Feb 2012.

The issue is, however, of implementation of these laws and the costs of availing these flexibilities. Firstly, the procedure for availing these flexibilities is unnecessarily complicated and burdensome. The procedure is time-consuming, involves substantial financial expense, and holds no guarantee of success.[15] Secondly, there are various practical implications for third world countries owing to which the flexibilities are, in many instances, only provided in the statute books and do not serve the desired practical purpose. Some of the implications for the developing world are briefly discussed here.

### 2.1 Foreign Direct Investment (FDI)[16]

The growth of local industry in developing countries is heavily dependent on investment that comes from outside the country.[17] Developing states may have to pay a heavy price for providing affordable access to medicines to their citizens by invoking compulsory licensing provisions. The pharmaceutical companies may mistrust the promises made by such nations to protect and enforce patent rights. If a nation is lacking security of intellectual property rights, pharmaceutical companies would think twice before making investments in that country.

Therefore, a country may lose a potential source of economic growth by issuance of compulsory licenses.[18] The patent holding pharmaceutical companies may withdraw from the states not fulfilling their commitments of patent protection; at least, they may withhold their new drugs.[19] Stringent patent protection on the other hand may lead to greater foreign direct investment.

[15] South Bulletin, 'The Doha Declaration on TRIPS', 8

[16] Foreign direct investment, in its classic definition, is defined 'as a company from one country making a physical investment into building a factory in another country. It is an investment abroad, usually where the company being invested in is controlled by the foreign corporation. It is a firm's transfer of assets from one country to another country in order to generate wealth for the owner of the assets'. In other words, it is a firm's transfer of assets from one country to another in order to generate wealth for the owner of the assets. An example of FDI is an American company taking a majority stake in a company in China. Passive investment through instruments such as notes, debt securities and bonds does not generally constitute FDI activities. For details visit <http://www.going-global.com/articles/understanding_foreign_direct_investment.htm> accessed April 26, 2012).

[17] Frederick M. Abbott, 'Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision', (2000), Quaker UNO160, doi:http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2005/08/30/000012009_20050830130225/Rendered/PDF/334260rev0pub.pdf, Accessed 23 Feb 2012.

[18] Cahoy, 'The Impact of Compulsory Licensing',284.

[19] Jerome H. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options, Journal of Law', (2009), 37 Medicine & Ethics 2, doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=34&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13, Accessed 23 Feb 2012

Thus, there is a straightforward relationship between foreign direct investment and intellectual property protection.[20]

For instance, Egypt, a middle-economy country with great potential for economic growth, has faced the consequences of its mishandled efforts to provide affordable access to pharmaceuticals to its citizens. In spite of its relatively high literacy rate, high English language proficiency of its citizens, liberal investment laws, relatively transparent tax system[21] and cheap labor force, Egypt has a suffered a continuous decline in foreign direct investment from '$948 million in 1987 to $598 million in 1995 to $428.2 million in 2001-2002'[22] because of its broad and ambiguous compulsory licensing provisions[23] and poor record of intellectual property protection.

In 2002, for example, Egyptian government first provided full patent protection to renowned Pfizer drug 'Viagra[24]' but only after two months, Egyptian government granted unlimited compulsory license in response to domestic pressure especially from local pharmaceutical manufacturers.[25] As a reaction to this decision, Pfizer cancelled its plan to construct an additional production facility in Egypt.[26] Moreover, in the wake of the same issue, the Pharmaceutical Research and Manufacturers Association of America (hereinafter PhRMA[27])

[20] Jamie Feldman, 'Compulsory Licenses: The Dangers Behind The Current Practice', 160, *doi*:http://www.hofstrajibl.org/media/blogs/a/Compulsory%20Licenses%20The%20Dangers%20behind%20the%20Current%20Practice.pdf, Accessed 23 March 2012accessed

[21] Robert Bird and Daniel R. Cahoy, 'The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach', (2008), 45 ABLJ,2, 20, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1092577, Accessed 20 Jan 2013.

[22] Cahoy, 'The Impact of Compulsory Licensing',301.

[23] Cahoy, 'The Impact of Compulsory Licensing', 23.

[24] Viagra is the brand name for Sildenafil citrate, and is used for treating erectile dysfunction and pulmonary arterial hypertension. Originally developed by scientists in Great Britain, it was brought onto the market by Pfizer Inc., a US pharmaceutical company.
For details visit doi:http://www.medicalnewstoday.com/articles/232912.php, accessed 27 April, 2012.

[25] Bird, 'Developing Nations', 211.

[26] Matthews, 'Renewing Healthy Competition',133.

[27] Pharmaceutical Research and Manufacturers of America (PhRMA), founded in 1958, 'is a trade group representing the pharmaceutical research and biopharmaceutical companies in the United States. PhRMA's stated mission is advocacy for public policies that encourage the discovery of new medicines for patients by pharmaceutical and biopharmaceutical research companies'.
For details visit <http://www.phrma.org/>, accessed 27 April, 2012.

told Egyptian representatives that pharmaceutical companies had cancelled their plans to invest $300 million in Egypt owing to weak intellectual property laws of the country.[28]

The developing countries may act collectively with other nations having similar problems and attempt to use compulsory licenses strategically through the use of collective action mechanism in order to minimize the loss of FDI through enhanced bargaining power.

### 2.2 Unilateral Trade Sanctions

The advanced countries have the tendency to ensure implementation of TRIPS in the developing world by their own unique mechanisms. For instance, the 'Special 301[29]' mechanism of the United States is used as an economic leverage to speed up the implementation of TRIPS Agreement in the developing world and to pressure the poorer countries to go beyond what is required under TRIPS. Initially, under Section 301[30] of the Trade Act of 1974, the US President was authorized to impose economic sanctions on states that burden or restrict US commerce.[31] Under Trade and Tariff Act 1984 and Omnibus Trade and Competitiveness Act 1988[32], Section 301 was amended to expand the scope of the provision to intellectual property.

[28] S. Aziz, 'Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer, and Foreign Direct Investment Policy: A Case Study of Egypt's Pharmaceutical Industry',(2003), 10 ILCL 1, 27 April,doi:https://litigationessentials.lexisnexis.com/webcd/app?action=DocumentDisplay&crawlid=1&srctype=smi&srcid=3B15&doctype=cite&docid=10+ILSA+J+Int%27l+%26+Comp+L+1&key=4bdb9af0b546c12bf48dd5833eaf6ac1, accessed 27 April 2012.

[29] The U.S, and western pharmaceutical companies have routinely used the Special 301 'mechanism for authorizing trade sanctions and lawsuits at the WTO and in domestic courts to oppose policies implemented by other countries that are unfavorable to pharmaceutical company interests'. *See generally* Sarah Boseley, 'How the U.S. Wields a Big Stick for Big Pharm', (2003), Guardian, doi:http://www.guardian.co.uk/world/2003/feb/18/aids.sarahboseley4, accessed27 27 April, 2012.

[30]The full text of the section can be accessed at <http://en.wikisource.org/wiki/Trade_Act_of_1974>, accessed20 20 Jan, 2013.

[31] Sean M. Flynn, 'Special 301 of The Trade Act of 1974 And Global Access to Medicines', (2010), 25 WCLR, 5, http://ssrn.com/abstract=1654011. Accessed 20 Jan 2013.

[32] Full text of the Omnibus Trade and Competitiveness Act 1988 is accessible at http://gsi.nist.gov/global/docs/Omnibus.pdf. accessed 20 20 Jan, 2013.

Present provision authorizes the office of the United States Trade Representatives (hereinafter USTR[33]) to review laws and practices of the US trading partners with regards to protection of intellectual property rights of United States citizens and companies[34] and prepare an annual Special 301 Report[35] on the basis of which sanctions can be imposed[36] on the countries that are non-serious in TRIPS compliance and have not revised their intellectual property laws.[37] USTR is authorized to place the states with inadequate intellectual property protection in 'watch list' or 'priority watch list' or 'priority foreign country category'[38] rendering them liable to face import restrictions.[39] These provisions provide for a 'fast track system' as USTR is required to decide within six months on what retaliatory action should be taken.[40] USTR is empowered to impose unilateral trade sanctions if demands of the US are not met.[41] Trade pressure is thus

[33] The Office of the United States Trade Representative (USTR) is the United States government agency responsible for developing and recommending United States trade policy to the president of the United States
For details visit <http://www.ustr.gov/>, accessed 27 April, 2012.

[34] Daniel J Gervais, 'Intellectual Property and Human Rights: Learning to Live Together', (2008), IPHR, 4.

[35] It is analyzed that 'the Special 301 Report is prepared annually by the Office of the United States Trade Representative (USTR) under Section 182 as amended of the Trade Act of 1974. The reports identify trade barriers to US companies and products due to the intellectual property laws in other countries. Each year the USTR must identify countries which do not provide adequate and effective protection of intellectual property rights or fair and equitable market access to United States persons that rely upon intellectual property rights'.
For details visit <http://www.ustr.gov/about-us/press-office/reports-and-publications/2011/2011-special-301-report>, accessed 27 April, 2012.

[36] The economic leverage applied by the US through Section 301 was in violation of Article XX(d) of the General Agreement on Tariffs and Trade (GATT) which provided signatory states flexibilities with regards to practices which USTR was addressing. Obama Administration pledged to promote access to affordable drugs in the third world, but the Reports released under Obama Administration do not suggest departure from previous US policy on trade and access to medicines. Full text of GATT is accessible at http://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf accessed January 13, 2013.

[37] Jillian Clare Cohen-Kohler and Lisa Forman, 'Addressing legal and political barriers to global pharmaceutical access: Options for remedying the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the imposition of TRIPS-plus standards, Health Economics', (2008), 3 Policy and Law, 241,accessed February 13, 2012, doi:http://journals.cambridge.org/action/displayFulltext?type=1&pdftype=1&fid=1914284&jid=HEP&volumeId=3&issueId=03&aid=1914276

[38] Michael A. Santoro, 'Human Rights and Human Needs: Diverse Moral Principles
Justifying Third World Access to Affordable HIV/AIDS Drugs', 5, http://ssrn.com/abstract=1269367. Accessed 20 Jan 2013.

[39] Andreas Rahmatian, 'Neo-Colonial Aspects of Global Intellectual Property Protection',(2009), 12 JWIP 1, 48, doi:10.1111/j.1747-1796.2008.00349.x. Accessed 20 Jan 2013.

[40] Heinz Klug, 'Law, Politics, and Access to Essential Medicines in Developing Countries', (2008), 1094 LSRP, 36(2), 213 , Http://ssrn.com/abstract=1464872, Accessed 20 Jan 2013.

[41] Flynn, 'Special 301 of The Trade Act of 1974', 4.

exerted on developing countries under the threat of sanctions under the 'Special 301' mechanism.

For instance, this mechanism was used against South Africa when in 1997, after the outbreak of the HIV/AIDS epidemic, it attempted to authorize parallel importation of affordable medicines through amendment in its patent law[42]. The United States tried to put pressure with a threat to impose unilateral trade sanctions against South Africa if the proposed legislation was passed.[43] The United States, however, had to withdraw trade pressure in this instance due to outrage around the world from the general public, human rights groups, AIDS activists and consumer advocates[44] that caused significant damage to the election campaign of Al Gore, the presidential candidate in the 2000 presidential elections in the US.[45]

In 2007, when Thailand announced use of compulsory license to improve access to drugs needed to treat heart diseases and AIDS, it was included in the 'Priority Watch List'.[46] More recently, the 'Special 301 Reports' issued in 2009 and 2010 pressed developing countries like Thailand and India to limit compulsory licenses for essential medicines and to restrict their freedom to define the scope of patentability.[47] Therefore, the fear of potential vulnerability to unilateral trade sanctions from the United States[48] prevents developing and least developed countries from exercising the flexibilities, exceptions and safeguards provided under TRIPS Agreement.[49] In 1999, use of Section 301 was reviewed by WTO Dispute Settlement Panel and

[42] Section 15C was inserted into the South African Medicines and Related Substances Control Act (MRSCA). The primary purpose of this amendment was to enable South Africa to benefit from lower prices abroad for the same drugs. For details visit http://www.ncbi.nlm.nih.gov/pubmed/19555268, accessed 27 April, 2012

[43] A. P. Valach, 'TRIPS Protecting the Rights of Patent Holders and Addressing Public Health Issues in Developing Countries', (2005), 4 Chicago. JIP 2, 27 April.doi:https://litigationessentials.lexisnexis.com/webcd/app?action=DocumentDisplay&crawlid=1&doctype=cite&docid=4+Chi.Kent+J.+Intell.+Prop.+156&srctype=smi&srcid=3B15&key=d5661df69a048447176c9a6a2dbef3c8, accessed 27 April, 2012.

[44] Forman, 'Addressing legal and political barriers',241.

[45] Third World Network, 'TRIPS, Drugs and Public Health: Issues and Proposals', (2001), 2 IPRS 26, , http://www.twnside.org.sg/title2/IPR/pdf/ipr02.pdf. Accessed 13 Feb 2012.

[46] Flynn, 'Special 301 of The Trade Act of 1974, 42.

[47] 'Human Rights Groups to Challenge Special 301', doi:http://a2knetwork.org/human-rights-groups-challenge-special-301, accessed 27 April, 2012).

[48] Colleen Chien, 'Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?', (2003), 18 BTLJ 895, http://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?article=1019&context=facpubs&sei-redir=1&referer=http%3A%2F%2Fscholar.google.com.pk%2Fscholar%3Fq%3Dcompulsory%2Blicensing%2Bof%2Bpatents%26hl%3Den%26btnG%3DSearch%26as_sdt%3D1%252C5%26as_sdtp%3Don#search=%22compulsory%20licensing%20patents%22, accessed 3 April 2012.

[49] Islam, 'The Generic Drug Deal', 690.

it held that without going through WTO dispute settlement process, US was not authorized to impose unilateral trade sanctions.[50] The continuation of Special 301 Program is a blithe disregard for the mandate of the WTO Dispute Settlement Panel and stands in stark contrast to the commitments made by the US under Doha Declaration.

Powerful countries like the United States should not be allowed to use the economic leverage - through Section 301- to deny legitimate flexibilities to the third world countries or to promote 'TRIPS plus' policies by pressing poorer countries to adopt stringent intellectual property rules that are not required under any international treaty or agreement. Council for TRIPS may take notice of any such practices which are not in conformity with the provisions of the TRIPS Agreement. The US may be asked to bring Special 301 Program into compliance with the WTO.

### 2.3 Bilateral Free Trade Agreements

While the developing world is facing practical problems in implementing TRIPS Agreement, the European Union and the United States of America have set new intellectual property standards going even further than TRIPS Agreement.[51] Under regional and bilateral free trade agreements with over 60 countries, the US has decided to implement TRIPS-plus[52] intellectual property standards. Central American Free Trade Agreement (CAFTA), North American Free Trade Agreement (NAFTA), U.S.-Jordan Free Trade Agreement (JUSFTA)[53], U.S.-Singapore Free Trade Agreement, U.S.-Chile Free Trade Agreement, U.S.-Australia Free Trade Agreement, U.S.-Morocco Free Trade Agreement, U.S.-Malaysia Free Trade Agreement, and U.S.-Korea Free Trade Agreement are just a few examples.[54] These agreements extend patent life beyond twenty years limit set by the TRIPS Agreement, limit use of compulsory licensing,

[50] Flynn, 'Special 301 of The Trade Act of 1974, 13.

[51] Puymbroeck, 'Basic Survival Needs' , 537.

[52] Many developing countries have been coming under pressure 'to enact or implement even tougher or more restrictive conditions in their patent laws than are required by the TRIPS Agreement – these are known as 'TRIPS plus' provisions. Countries are by no means obliged by international law to do this, but many states have had no choice but to adopt these, as part of trade agreements with the United States or the European Union. These have a disastrous impact on access to medicines'. For further details visit <http://www.msfaccess.org/content/trips-trips-plus-and-doha>, accessed 27 April, 2012).

[53] See generally

[54] Chuan-feng Wu, 'Raising The Right To Health Concerns Within The Framework Of International Intellectual Property Law', 156, http://ssrn.com/abstract=1578865, Accessed 20 Jan 2013.

prohibit parallel imports, and discourage market entry of generics even after the expiration of patent protection.[55]

It might be surprising to note that many of these countries are developing countries already facing the issues of availability of necessary drugs. Governments of poorer countries consent to enter into these agreements because they prefer economic growth over access to health care.[56] In return of these agreements that impair public health, the third world countries get access to Western investment, access to large industrialized country markets, low tariffs on particular goods, and foreign aid. Another reason behind willingness of third world countries to enter into such agreements may be threat of bilateral trade sanctions which deprives developing countries of any bargaining power during negotiations and hardly leaves any room for poorer countries to say no to such agreements.[57]

These additional trade-enforced restrictions -outside WTO and WIPO- further aggravate the public health situation in third world countries.[58] The U.S. government uses the aforementioned Special 301 Program to promote these TRIPS-Plus policies.[59] The situation may become grimmer if the generic drug suppliers like India and Thailand bow to foreign pressure and enter into TRIPS-plus agreements that prohibit the use of non-voluntary licenses for export.[60]

The economic coercion in the form of bilateral and regional TRIPS-plus agreements, therefore, undermines the existing TRIPS safeguards, exceptions, and flexibilities.[61] International institutions like WTO and WIPO may play their role to maintain a balance between intellectual property rights and public health because there is an asymmetric power relationship between developed and developing world.

[55] Forman, 'Addressing legal and political barriers', 241.

[56] Lisa Forman, 'Trade Rules, Intellectual Property, And the Right to Health', 342, http://onlinelibrary.wiley.com/doi/10.1111/j.1747-7093.2007.000103.x/pdf, Accessed 20 Jan 2013.

[57] *Ibid.* 343.

[58] Gervais, 'Intellectual Property and Human Rights', 20.

[59] Flynn, 'Special 301 of The Trade Act of 1974', 15.

[60] *Ibid.*

[61] South Bulletin, 'The Doha Declaration on TRIPS', 7.

### 2.4 External Transit Control of Generics

Confiscation of legitimate generics by customs officials has become another hurdle in the access to drugs. The powerful countries encourage their border officials to seize any products that allegedly infringe intellectual property rights. Out of twenty shipments of generic medicines seized by border officials of countries like France, Germany and Netherlands since late 2008, nineteen were lawfully manufactured in India and legally exported to poorer countries.[62] These medicines were not intended for consumption in the EU countries; they were only passing through these countries and there was no evidence of the fraudulent diversion of these medicines to the national markets of EU countries[63], even then they were confiscated for allegedly violating territorial patents of EU countries.[64] Similarly, in March 2009, a shipment funded by UNITAID[65] was stopped by Dutch border officials under EU Regulation 1383/2003[66] for allegedly containing counterfeit drugs. According to UNITAID, the medication 'Abacavir' was not counterfeit and confiscation was unlawful.[67]

Generic producers like India and Brazil consider external transit control of generics inconsistent with TRIPS and Doha Declaration and an impediment for access to drugs.[68] WTO member states are required to adopt border measures under Article 51 to 60 of the TRIPS but these provisions apply to only 'counterfeit trademark and pirated copyright goods'[69]. These provisions do not cover other forms of intellectual property rights such as patents.[70] Moreover, Article 51 is confined to '*importation* of counterfeit trademark or pirated copyright goods'. From language of Article 51 it is not clear whether or not border measures required under TRIPS

[62] Medicines that were confiscated included Losartan –a cardiovascular disease medicine- intended for Brazil and Abacavir, a key anti-retroviral medicine intended for Nigeria. See generally Flynn, 'Special 301 of The Trade Act of 1974', 47.

[63] Micara, 'TRIPS-plus Border Measures and Access to Medicines', 77.

[64] Flynn, 'Special 301 of The Trade Act of 1974', 47.

[65] UNITAID is an international drug purchase facility that was founded in 2006 on the initiative of France and Brazil to provide sustainable and long term funding for access to drugs for the treatment of Malaria, tuberculosis and HIV/AIDS in the third world. For details visit http://www.unitaid.eu/. accessed 19 Jan, 2013.

[66] Full text of EU Regulation 1383/2003 is accessible at http://www.wipo.int/wipolex/en/details.jsp?id=1455. accessed 19 Jan, 2013.

[67] Micara, 'TRIPS-plus Border Measures and Access to Medicines' 73.

[68] *Ibid*, 74

[69] Text from Article 51 of TRIPS . Similarly, Article 61 mentions 'cases of wilful trademark counterfeiting or copyright piracy on a commercial scale'. Full text of TRIPS is accessible at <http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm> accessed 19 Jan, 2013.

[70] Henning Grosse Ruse-Khan, 'China—Intellectual Property Rights: Implications For the TRIPS-Plus Border Measures', (2010), 13 JWIP 5, 623, doi:10.1111/j.1747-1796.2010.00405.x, Accessed 20 Jan 2013.

extend to infringing exports.[71] In 2009, WTO Dispute Settlement Panel confirmed that 'there is no obligation to apply the requirements of Article 59 to goods destined for exportation'.[72] Moreover, text of Article 59 also confirms the same as in its second sentence it refers to 're-exportation' of the infringing goods and not 'exportation'.

If border measures are extended to patent infringements going beyond what is required by TRIPS, there is a fair chance that most of the confiscations under the suspicion of patent infringement may be wrongful because violations patent rights cannot be determined by border officials or police from mere appearance of products. Moreover, external transit control of generics is in contrast with the objectives of TRIPS stated in Article 7[73] of TRIPS. It was claimed by India that 'the seizures run counter to the spirit of the TRIPS Agreement and the resolution 2002/31 of the commission on Human Rights on the right to enjoy the highest standards of physical and mental health'.[74] International institutions should not allow powerful countries to threaten lives of people and impede legitimate trade of generic drugs on the basis of their mere suspicion or speculation.

[71] *Ibid*, 624.

[72] Dispute Settlement Reports, ( 2009), 7.224,. 2172 , http://books.google.com.pk/books?id=6wpuDIDYEBEC&pg=PA2172&lpg=PA2172&dq=there+is+no+obligation+to+apply+the+requirements+of+Article+59+to+good+destined+for+exportation&source=bl&ots=Xy5uGaWjzR&sig=mW4Lfk1iYKSTHi-2J-1NhT-ZBDY&hl=en&sa=X&ei=tHH7UPLjK8HDhAfzroAQ&sqi=2&ved=0CCkQ6AEwAA#v=onepage&q=there%20is%20no%20obligation%20to%20apply%20the%20requirements%20of%20Article%2059%20to%20good%20destined%20for%20exportation&f=false. accessed 20 Jan, 2013.

[73] Article 7 of TRIPS stipulates: 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'. Full text of TRIPS is accessible at <http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm> accessed 19 Jan, 2013.

[74] Swarna Latha Soppadandi, 'New Hurdles For Access To Medicines: A Human Rights Perspective Of The Ec-Regulation 1383/2003 And The Generic Drug Seizure Cases', (2010), AUW Col. Of Law.5, http://works.bepress.com/cgi/viewcontent.cgi?article=1000&context=swarna_latha_soppadandi, Accessed 20 Jan 2013

### 2.5 The Risk of Retaliatory Action

Political pressure exerted by developed countries prevents developing and least developed countries from exercising their rights under TRIPS Agreement.[75] Faced with the risk of retaliatory action from developed countries, their giant corporations, and industry lobbies, the third world countries do not feel free to enact policies and laws on parallel imports and compulsory licensing for essential life-saving drugs.[76] They have been provided rights under TRIPS but the decision to make use of these rights is plagued by political considerations.[77]

For instance, in 2002, when South Korea decided to grant compulsory license for Gleevec, the US government pressured her not to do so. Similarly, in 2006, Pfizer pressured Philippine when she decided to parallel import a generic version of Norvasc.[78] In the same year, when Thailand[79] granted compulsory license for *efavirenz*, the United States, with the threat of high tariffs for Thai exports[80], exerted pressure on Thailand to ban parallel imports and to revoke the compulsory license and negotiate with Merck.[81] The pharmaceutical industry also reacted strongly against the Thai government's efforts to provide affordable access to necessary drugs.[82] The giant pharmaceutical companies are not only well funded but also well organized; they are supported by powerful governments like the United States and the European Union[83], and are,

[75] For instance, in the summer of 2007, the government of Bangladesh got letters from European Union trade commissioner Peter Mandelson and U.S. Ambassador to Thailand, Ralph Boyce, after it announced plans for a compulsory license for HIV drugs.
For details visit <http://www.worldcrunch.com/drug-companies-battle-against-indian-pharmaceutical-pirates/4890>,

[76] Third World Network, 'TRIPS, Drugs and Public Health', 26.

[77] South Bulletin, 'The Doha Declaration on TRIPS', 7.

[78] Forman, 'Trade Rules, Intellectual Property', 342.

[79] Government of Thailand issed order, 'Citing the high drug prices and its obligation to provide access to essential medicines, Thailand issued government use (GU) orders for three drugs on the national essential medicines list: *efavirenz* (November 2006), *lopinavir/ritonavir* (20 Jan07), and *clopidogrel*, a heart disease drug marketed as Plavix by BMS (20 Jan07). The patent holders were entitled to a royalty of 0.5% of the total sales of the generic product. The GU authorised the Governmental Pharmaceutical Organisation (a Thai State-owned enterprise) to import or produce generic versions of these products for non-commercial use in the public health sector. Initially the GU was used for importation'. For details visit <http://www.keionline.org/content/view/90/1>, accessed 27 April, 2012.

[80] Third World Network, 'TRIPS, Drugs and Public Health', 26.

[81] South Bulletin, 'The Doha Declaration on TRIPS', 7.

[82] 'Compulsory Licensing And The Anti-Competitive Effects of Patents for Pharmaceutical Products: From A Developing Countries' Perspective', 56.

[83] Bird, 'Developing Nations', 214.

therefore, fully capable of exerting formidable pressure on third world countries.[84] The International Federation of Pharmaceutical Manufacturers Association (IFPMA) openly condemns issuance of non-voluntary licenses.[85]

Developing countries may show unity for their common concerns irrespective of their geographical variation and difference in level of development. Moreover, they may form alliances with developed states and even with international health organizations and non-governmental organization (NGOs) to constrain extra-legal pressure. Through unity, coordinated behavior, and adoption of collaborative position, developing countries may extract more fair prices from patent holders through collective bargaining.

Further, effective use of media and mobilization of Non-Governmental Organizations and human rights activists can be very useful in instances where global powers and giant multinational pharmaceutical companies try to place corporate interests above the grave medical concerns during a health crisis. Media and human rights activists may present the issue of access to drugs as an issue of *ordre public*[86] or morality in order to shape public opinion in favor of poor countries. Multi-national corporations (MNCs) are normally very much concerned about public opinion and their reputation or perception among consumers because any negative impression about these companies has an adverse effect on sale of their products.

Furthermore, developing countries may use the forum of WTO's Dispute Settlement Body (DSB[87]) to resolve disputes relating to compulsory licensing of patents. Developed states, owing

[84] For instance, when Thailand issued a compulsory license for Kaletra, an AIDS medication produced by Abbot, the U.S. drug maker responded by denying Thai patients access to its other life-saving drugs. For details visit <http://www.worldcrunch.com/drug-companies-battle-against-indian-pharmaceutical-pirates/4890>, accessed June 4, 2012.

[85] Muhammad Asif Awan, '*Pakistani Pharmaceutical Industry* in *WTO regime-Issues* and *Prospects*', (2005), 1 JQTM 9, doi:http://pu.edu.pk/images/publication/PPI_in_WTO_%20regime-Issues_and_Prospects.pdf, accessed 4 June 2012.

[86] The public policy doctrine or ordre public concerns the body of principles that underpin the operation of legal systems in each state. This addresses the social, moral and economic values that tie a society together. laws are most likely to be effective when they are consistent with the most generally accepted societal norms and reflect the collective morality of the society. Ordre public encompasses the protection of public security and the physical integrity of individuals as part of society.
For details visit <http://www.iprsonline.org/unctadictsd/docs/RB2.5_Patents_2.5.3_update.pdf> accessed June 2, 2012.

[87] The Dispute Settlement Body (DSB) of the World Trade Organization (WTO) makes decisions on trade disputes between governments that are adjudicated by the Organization. The DSB is, in effect, a session of the General Council of the WTO: that is, all of the representatives of the WTO member governments, usually at ambassadorial level, meeting together. It decides the outcome of a trade dispute on the recommendation of a Dispute Panel.
For details visit <http://en.wikipedia.org/wiki/Dispute_Settlement_Body> accessed June 2, 2012.

to the risk of a binding negative decision, are normally reluctant to use the DSB forum; they rather rely on political and economic pressure to achieve their desired results in such disputes.

### 2.6 Technology Transfer

Article 66, paragraph 2 of the TRIPS Agreement stipulates:

> 'Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.'[88]

Moreover, paragraph 7 of the Declaration on TRIPS Agreement and Public Health (Doha Declaration adopted on 14 November 2001) 'reaffirms the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2'[89] of the TRIPS Agreement.

Everyone has a right to benefit from scientific inventions and technological advancements.[90] More importantly, economic development of third world countries, especially those with adequately developed technology infrastructure and a strong base of human capital, relies heavily on transfer of technology from industrialized economies who almost enjoy a monopoly on the development of new knowledge and high-level technologies. No intellectual property rights protection poses a threat of imitation or reverse engineering[91] of high-technology imported products. Stringent patent protection, on the other hand, can cause inordinate delay in technology transfer to the developing world[92] because the patent holder enjoying monopoly over the new technology excludes all others rendering the invention beyond the reach of poor

[88] Article 66, paragraph 2 of the TRIPS Agreement. Full text of TRIPS Agreement is available online at <http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm> accessed May 5, 2012.

[89] Paragraph 7 of the Declaration on TRIPS Agreement and Public Health. Full text of Doha Declaration is available at <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed May 5, 2012.

[90] Islam, 'The Generic Drug Deal', 688.

[91] Reverse engineering is the process of discovering the technological principles of a device, object, or system through analysis of its structure, function, and operation and to apply the findings to produce something similar. For details visit <http://en.wikipedia.org/wiki/Reverse_engineering> accessed May 5, 2012.

[92] Dilip K. DAS, 'Intellectual Property Rights and the Doha Round',(2005), JWIP, 43doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2005.tb00236.x/pdf, accessed 13 Feb 2012.

masses in the third world.[93] Edwin Mansfield[94], an American professor of economics, concluded that:

> The strength or weakness of a country's system of intellectual property protection seems to have a substantial effect, particularly in high-technology industries, on the kinds of technology transferred by many U.S firms to that country.[95]

TRIPS Agreement was expected to give due importance to the issue of transfer of technology from developed to underprivileged countries. But TRIPS Agreement did not create mandatory obligations for transfer of technology.[96] A corresponding obligation was created under aforementioned article 66.2 of the TRIPS Agreement, but practically advanced nations did not comply with article 66.2. This corresponding obligation was reaffirmed in 2001 in Doha Declaration, again without producing desired results. Again, the TRIPS Council, in 2003, adopted a decision on implementation of article 66.2 and devised a reporting mechanism under which developed nations were supposed to submit reports to the TRIPS Council on actions taken or planned by them to fulfill their commitments under article 66.2. Again, this mechanism could not produce desired results because most of the reports submitted failed to meet the reporting criteria.[97] This attitude of developed nations is against the objectives of the TRIPS that are set down in Article 7 of the TRIPS Agreement. Article 7 of TRIPS clearly stipulates that:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of the producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[98]

[93] Islam, 'The Generic Drug Deal', 688.

[94] Edwin Mansfield (1930–1997) was a professor of economics at University of Pennsylvania from 1964 and until his death. From 1985 he was also a director of the Center for Economics and Technology. Edwin Mansfield is best known for his scientific results concerning technological change / diffusion of innovations, and also for his textbooks on microeconomics, managerial economics, and econometrics. For details visit <http://en.wikipedia.org/wiki/Edwin_Mansfield> accessed May 5, 2012.

[95] Rozek, 'The Effects of Compulsory Licensing',901.

[96] Islam, 'The Generic Drug Deal', 688.

[97] South Bulletin, 'The Doha Declaration on TRIPS', 10.

[98] Full text of TRIPS Agreement is available online at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf accessed January 13,2013.

In the absence of mandatory obligations for transfer of technology, the developing countries may develop their patent regime in such a manner as to strike a balance between IPRs protection and their economic development goals. Compulsory licenses can therefore be used as one of the channels to improve flows of technology to the third world remaining within the flexibilities provided under TRIPS Agreement.

Advanced states may be asked to fulfill their commitments made under article 66.2 of the TRIPS Agreement. TRIPS may be revised to include mandatory obligations for transfer of property. Developing countries may compose themselves into a homogeneous group in the WTO to raise a common voice for their concerns if the provisions safeguarding their legitimate interests are not complied with by the technologically advanced states.

### 2.7 Lack of Technical Expertise

In order to use flexibilities provided under TRIPS Agreement and Doha Declaration, member states need to review and amend their national laws. Lack of technical expertise in the field of intellectual property in the underprivileged countries has been an impediment in fully availing the flexibilities provided under TRIPS by incorporating them in the national laws.[99]

TRIPS Agreement's provisions especially those regarding compulsory licenses and parallel importation, are coupled with conditions which make them difficult to invoke effectively and speedily. The countries which do not have adequate technical expertise face difficulties in interpretation and implementation of the TRIPS provisions that lack legal clarity and common understanding.[100] Necessary technical assistance should therefore be provided to developing countries in relation to intellectual property in order to enable them to reform their legal and administrative systems. TRIPS Agreement provides for this technical cooperation. Article 67 of the TRIPS Agreement stipulates:

> In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favor of developing and least-developed country Members....[101]

[99] South Bulletin, 'The Doha Declaration on TRIPS', 16.

[100] Third World Network, 'TRIPS, Drugs and Public Health', *125.*

[101] Article 67 of the TRIPS Agreement. Full text of TRIPS Agreement is available online at <http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm> accessed May 5, 2012.

In 1996, TRIPS Council agreed that the developed country members would provide annually information about the steps taken by them to fulfill their commitments made under article 67. In addition to individual member states, Intergovernmental organizations like World Intellectual Property Organization (WIPO) and World Trade Organization (WTO) may undertake capacity building work to ensure technical assistance to developing countries that lack the capacity to reform their domestic IPRs regimes to avail TRIPS-compatible flexibilities.[102]

### 2.8 High Litigation Costs

The cost of patent litigation is not trivial.[103] Owing to high litigation costs, third world countries are extremely reluctant to become party to patent litigation.[104] Drug and health patents are the most litigated patents[105] and developing and least developed countries can hardly be expected to have significant capacity and economic incentive to litigate claims against authorization of parallel importation and grant of non-voluntary licenses.

In the aforementioned case of South Africa, for instance, when in 1997, after the outbreak of the HIV/AIDS epidemic, South African government attempted to authorize parallel importation of affordable medicines through a controversial legislative proposal,[106] it triggered reaction of pharmaceutical companies. Thirty nine multinationals, being the stakeholders in this matter, moved the High Court of South Africa whereby they challenged the constitutionality of the proposed amendment.[107]

[102] South Bulletin, 'The Doha Declaration on TRIPS', 11.

[103] In December 1998, the New York Times reported that the median cost of U.S patent litigation was $1.2 million per side, whereas costs of litigation in complex cases were much higher. The largest component of these costs is attorney's fee but it also includes expert witness fees, travel costs, and document management and production costs. For details visit <http://www.harborlaw.com/newsletters/november.pdf> accessed May 5, 2012.

[104] James Love, 'Compulsory Licensing: Models for State Practices in Developing Countries, Access to medicine and Complince with the WTO TRIPS accord', (2004), 5, doi:http://www.twnside.org.sg/title2/IPR/pdf/ipr06.pdf, accessed 20 March 2012.

[105] Ibid, 4.

[106] Section 15C was inserted into the South African Medicines and Related Substances Control Act (MRSCA). The primary purpose of this amendment was to enable South Africa to benefit from lower prices abroad for the same drugs. For details visit <http://www.ncbi.nlm.nih.gov/pubmed/19555268>, accessed 27 April, 2012.

[107] *'Ofeibea Quist-Arcton,* South Africa: Battle Against Pharmaceutical Giants Continues', 2001. For details visit <http://allafrica.com/stories/200104170346.html> accessed May 23, 2012.

In this case, the multinationals had to drop their case due to outrage around the world from the general public, human rights groups, AIDS activists and consumer advocates[108]; otherwise one can imagine the potential litigation cost in this case. Thirty-nine multinational pharmaceutical companies, including giants like Bristol-Myers Squibb[109] could easily afford the litigation cost but the governments of developing countries do not see much economic incentive in bearing such heavy costs of corporate litigation.

In addition to the legal fee, such disputes impose considerable time costs on developing countries.[110] Although challenge was withdrawn in the aforementioned case due to intense public pressure, the potential threat of similar challenges still exists.[111] Governments of third world countries may therefore be reluctant to invoke compulsory licensing provisions keeping in view the considerably high potential costs of patent litigation and time costs. This consequently restricts the use of compulsory licensing.

The giant multinational pharmaceutical companies have money and legal firepower to put a pressure on third world countries. In order to avoid spending huge amounts on costly patent litigation, the poor countries should do their homework and comply with national and international law on the issue before invoking compulsory licensing provisions. They should try their best to know and perform their obligations before resorting to compulsory licensing. They should enhance their technical expertise in the field of intellectual property laws to know the nitty gritty of the compulsory licensing mechanism and the legal ramifications involved in its use.

### 2.9 Insufficient Progress during Transition Period

The TRIPS Agreement came into effect on 1st of January in 1995. The third world countries were, however, provided extended period for compliance with TRIPS Agreement keeping in view their technical, administrative, financial, and economic constraints.[112] Developing

[108] Third World Network, 'TRIPS, Drugs and Public Health', 25.

[109] Bristol-Myers Squibb, is a pharmaceutical company, headquartered in New York City. The company was formed in 1989, following the merger of its predecessors Bristol-Myers and the Squibb Corporation. Squibb was founded in 1858 in New York, while Bristol-Myers was founded in 1887 also in New York
For further details visit <http://en.wikipedia.org/wiki/Bristol-Myers_Squibb>,accessed May 23, 2012.

[110] Bird, 'Developing Nations', 213.

[111] Third World Network, 'TRIPS, Drugs and Public Health', 26.

[112] WTO and the TRIPS Agreement. Available online at
<http://www.who.int/medicines/areas/policy/wto_trips/en/index.html> accessed May 24, 2012.

countries were granted an extended period up to January 1, 2000. The least developed countries were given an initial extended period up to January 1, 2006. In November 2005, however, the WTO member countries granted further transition period until July 1, 2013.[113] Later, the deadline for least developed countries was further extended to January 1, 2016.[114]

During the transition period, developing and least developed countries were exempted from the obligation of patent protection and data protection with regards to pharmaceutical products.[115] The purpose behind granting this extended period was to provide time to these countries to make their national legislation and local practices compatible with the TRIPS provisions and to develop their technological base before full compliance with the TRIPS obligations. The transition period is even more significant from a public health perspective.[116] These countries were provided time to develop their local pharmaceutical manufacturing capacity to avoid various practical implications of TRIPS. But the third world especially the least developed countries failed to fully utilize the transition period.

Financial constraints may be an obvious reason for not achieving the fundamental objectives of the transition period. The United States' annual expenditure on its patent and trademark office is about $1 billion.[117] Other developed countries also spend huge amounts of money on their patent examination mechanism. Third world countries, especially least developed countries, can hardly afford to allocate huge sums in this regard.

Moreover, third world countries were dependent on the developed world to achieve objectives of the transition period because technology transfer was an integral component of the extended period. According to Article 66, paragraph 2 of the TRIPS and paragraph 7 of the Doha Declaration, the technologically advanced states are obligated to provide incentives to encourage transfer of technology to the least developed countries.[118] It has been shown by the

[113] Richard J. Hunter: Hector R. Lozada: Frank Giarratano and Daniel Jenkins, 'Compulsory Licensing: A Major IP Issue in International Business Today?', *European Journal of Social Sciences – Volume 11, Number 3* (2009), 372, last accessed date March 21, 2012, doi:http://www.eurojournals.com/ejss_11_3_03.pdf.,

[114] Bird, 'Developing Nations', 211.

[115] United Nations Industrial Development Organization, 'Transition Period for Least Developed Countries', Available online at <http://www.local-pharma-production.net/index.php?id=98> , accessed May 24, 2012.

[116] South Perspectives, 'The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?', (2006), last accessed date March 23,2012. http://www.southcentre.org/index.php?option=com_content&view=article&id=70%3Athe-use-of-flexibilities-in-trips-by-developing-countries-can-they-promote-access-to-medicines&catid=41%3Ainnovation-technology-and-patent-policy&Itemid=67&lang=en.

[117] Love, 'Compulsory Licensing: Models for State Practices', 4.

[118] South Bulletin, 'The Doha Declaration on TRIPS', 10.

available evidence that technologically advanced states failed to comply with Article 66, paragraph 2 of the TRIPS Agreement.[119]

Thus, not only third world countries but also the developed countries are equally responsible for not achieving the fundamental objectives of the transition period because they too did not meet their commitments made under Article 66.2 of the TRIPS Agreement. Article 68 of the TRIPS Agreement envisages establishment of 'Council for TRIPS' with the duty to monitor the operation of TRIPS and compliance of member states with the provisions of the Agreement.[120] Council for TRIPS should make sure that legitimate interests of the poorer countries are protected and provisions of the TRIPS are complied with by the powerful states.

### 2.10 Risk of Counterfeit Drugs[121]

Although, so far, the focus has been on implications which restrict poor countries from availing the flexibilities provided under the TRIPS Agreement, third world countries face certain problems even if they successfully invoke the compulsory licensing provisions despite all economic and political pressure.

Risk of falsely labeled substandard counterfeit drugs with little or no therapeutic value is one such issue associated with the use of compulsory licensing in the third world countries. Purpose of granting a compulsory license by government of a poor country may be to promote access to affordable drugs for its citizens with low purchasing power, but this sometimes results in

[119] UNAIDS , 'Implementation of TRIPS and Access to Medicines for HIV after 20 Jan16: Strategies and Options for Least Developed Countries', (2011), 11,doi:http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf , accessed 20 March 2012.

[120] Odman, 'Using Trips To Make The Innovation Process Work', 27.

[121] Counterfeit drugs are products that are presented in such a way as to look like legitimate or genuine products although they are not that product. A counterfeit drug may contain inappropriate quantities of active ingredients, may contain ingredients that are not on the label, or may be supplied with inaccurate or fake packaging and labeling. For further details visit <http://en.wikipedia.org/wiki/Counterfeit_medications> accessed May 24, 2012.

prevalence of fake or counterfeit drugs. This mixing of fake and generic medicines[122] undermines access to necessary medicines for underprivileged masses in the developing world.

Most of the African countries lack the capacity to manufacture drugs. They therefore import generic medicines from generic producers and are particularly concerned about falsified substandard drugs. According to a survey conducted by World Health Organization (WHO), about 30 percent of the sampled medicines for curing malaria taken from Ethiopia, Kenya, Ghana, Cameroon, Nigeria, and Tanzania did not meet international quality standards.[123]

The situation is not much different in the rest of the third world. World Health Organization (WHO) estimated that 25 percent of the total medicine consumed in the third world countries is counterfeit or substandard.[124] The buyers in the low income countries can hardly distinguish between the generic copies of the patented drugs and the counterfeit or fake drugs. They purchase the falsified drugs which may prove silent killers because the counterfeit medicines are not only devoid of effect but may also contain toxic substances.

Consequently, anti-counterfeit laws are being proposed or enacted by many poor countries; Kenyan Anti-Counterfeit Act of 2008[125] is just one example. Efforts are being made at international level as well to curb global trade of fake products. In October 2011, for instance, developed countries including Australia, New Zealand, Japan, Canada, and the United States

[122] Generic medicines are legitimately produced medicines that are the same as original brand name products with the same active ingredients but that are manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights. Although they may not be associated with a particular company, generic drugs are subject to the regulations of the governments of countries where they are dispensed. Generic drugs are labeled with the name of the manufacturer and the adopted name (nonproprietary name) of the drug. Since generic manufacturers do not bear any research and development cost but only the manufacturing cost, the drug produced under the compulsory license will almost always be cheaper than the patented drug.

For details visit <http://en.wikipedia.org/wiki/Generic_drug> accessed May 24, 2012.

[123] *Ibid* 2.

[124]World Health Organization, "Substandard and Counterfeit Medicines", (2003doi:http://www.who.int/mediacentre/factsheets/2003/fs275/en/, accessed 24 May 2012.

[125] In 2010, the High Court of Kenya suspended implementation of the Act 'in as far as it applies to generic medicines.' The case was filed by three people living with HIV challenging sections 2, 32 and 34 of the Act as unconstitutional. For details visit <http://afro-ip.blogspot.com/2010/04/kenyas-anticounterfeit-law-suspended.html> accessed May 24, 2012.
In August 2010, the Kenyan Anti-Counterfeit Act of 2008 was replaced by the Kenyan Anti-Counterfeit Regulations 2010. For details visit
<http://www.coulsonharney.com/LawArticles/Documents/THE%20KENYAN%20ANTI-COUNTERFEIT%20REGULATIONS%202010%20-%2026102010.pdf> accessed May 24, 2012.

signed a new international treaty called the Anti-Counterfeiting Trade Agreement (ACTA).[126] In January 2012, the European Union and 22 member countries of the European Union also signed this treaty.

Practically, so far, developing world has not been able to curb the prevalence of falsified counterfeit drugs. Some critics of compulsory licensing even suggest that instead of relying on compulsory licensing to gain access to drugs, governments of developing countries should buy patented products directly from the manufacturers at negotiated prices.[127]

Risk of illness or death from the use of falsely labeled substandard counterfeit drugs with little or no therapeutic value can be reduced to some extent through consumer education about identification and hazards of counterfeit drugs. A consumer is less likely to buy a fake drug if he is familiar with his medicine and knows about side effects of the bogus drug. Moreover, governments of developing countries may acquire and use modern technologies to identify the counterfeit drugs from genuine drugs because both may look exactly the same to the naked eye. Further, manufacturers of branded drugs may use distinguishable features –like unique stickers which cannot be imitated easily- on packaging to help the consumer distinguish between fake and genuine drugs. Furthermore, the law enforcement agencies should take action against laboratories manufacturing counterfeit drugs and pharmacies selling these fake drugs.

### 2.11 Reducing Incentives to Innovate

Reduction in incentives to innovate is yet another drawback of non-voluntary licensing faced by third world countries. Not only use but also the predictability of compulsory licensing has a negative impact on pharmaceutical innovation. The drugs can be divided into two broad categories: First, 'global drugs' like cancer drugs and HIV/AIDS vaccines that are primarily created for rich markets but are also needed by the developing world. Second, the drugs that are needed only by poorer countries like drugs to treat tuberculosis or malaria.[128] The drugs specific to third world are not priority of multinational pharmaceutical companies because of less financial gain. Threat of non-voluntary licensing in the developing world further adds to the concerns of the multinationals rendering them extremely reluctant to initiate and carry out

[126] DG EXPO Policy Department, 'The Anti-Counterfeiting Trade Agreement (ACTA): An Assessment', (2008), European Parliament, 8, doi:http://www.europarl.europa.eu/committees/en/studiesdownload.html?languageDocument=EN&file=43731, accessed 20 March 2012.

[127] 'Fake Drug Progress in Kenya and Compulsory Licensing', (2010), Available online at <http://afro-ip.blogspot.com/2010/09/fake-drug-progess-in-kenya-and.html> , accessed May 24, 2012.

[128] Chien, 'Cheap Drugs at What Price', 892.

research and development investment on pharmaceutical products specific to the poorer countries.

When the multinationals are not willing to invest in poverty-related diseases because they do not consider it a profitable investment, private research-based pharmaceutical companies of the developing countries may play a vital role. But unnecessary use of non-voluntary licensing by the developing countries may adversely affect the private research-based pharmaceutical industry of the country.[129] By establishing an appropriate correlation between profit and risk through careful use of compulsory licensing, developing countries may encourage their private research-based pharmaceutical companies to invest in the third world specific ailments in the hope of monetary gain.[130]

Appropriate laws and regulations should therefore be adopted by developing countries to make use of TRIPS flexibilities. Courts and patent offices of poor countries should act as vigilant stewards of public interest. No doubt developing countries can invoke compulsory licensing provisions to improve access to essential life-saving medicines, but this is a short term and emergency solution to public health crisis. Developing countries should use it carefully to avoid undesirable potential consequences.

Developing countries should use all other available options to promote greater access before resorting to compulsory licensing only in grave situations of public health crisis. For instance, tariff barriers have effect on the prices of products imported into the country. High import tariff and other trade barriers raise the price of drugs and consequently have a disastrous effect on access to drugs. States faced with the public health crisis may lower tariffs on necessary medicines to reduce prices of such medicines. Similarly, governments of developing countries may negotiate with the patented pharmaceutical manufacturers and request them to lower the prices on humanitarian grounds in situations of public health crisis. If the pharmaceutical companies are willing to help, governments of developing countries may buy patented products directly from the manufacturers at negotiated prices.

## 3 Conclusion

Though WTO, under TRIPS, provided flexibilities to developing and under developed countries and over the period of time tried to facilitate the poorer countries to use such

[129] Reichman, 'Compulsory Licensing of Patented', 7.

[130] Ibid, 4.

flexibilities, still a lot of steps need to be taken to facilitate the member countries to effectively use the safeguards provided under TRIPS in order to improve availability of necessary drugs at affordable prices.

No doubt, compulsory licensing and parallel importation are effective legitimate tools in the hands of developing and least developed nations to provide essential drugs to their citizens; in order to avoid costly and needless litigation and to minimize negative effects, this tool should be used with extreme caution only after giving due consideration to compliance with municipal and international law and keeping in view the external political, social, and economic conditions.

Use of TRIPS flexibilities may generate undesirable long-term effects on the economic development of the country. The reaction of the owners of a patent may be so serious that a developing or under developed country may face economic consequences. The pharmaceutical companies may mistrust such states and decide not to engage in foreign direct investment (FDI). This loss of foreign investment may be a heavy blow for the economic growth of a poorer country. Thus, a state may have to pay quite a heavy price for improving access to needed medicines for its masses.

To sum up, there are implementation gaps between theory and practice of TRIPS flexibilities; WTO member states have been provided flexibilities under TRIPS Agreement but third world countries are not able to avail the flexibilities due to numerous practical implications which restrict them from availing the legitimate flexibilities. The flexibilities are, in many instances, only provided in the statute books and do not serve the desired practical purpose.